

510(k) Summary

JUN 23 2005

OFFICIAL CONTACT: Lisa A. Ewing
Regulatory Affairs Specialist
MEDRAD, Inc.
One Medrad Drive
Indianola, PA 15051
(412) 767-2400 Ext. 3780

CLASSIFICATION NAME: Magnetic Resonance Diagnostic Device
(21 CFR 892.1000, Product Code MOS)

COMMON NAME(S): Magnetic Resonance Coil

PROPRIETARY NAME: 3.0T Prostate Imaging System

PREDICATE DEVICES: MEDRAD MRInnervu Endorectal Prostate Coil
with Probe Interface Device (K926571)
MEDRAD Flex Interface Device (K971380)

INTENDED USE: The 3.0T Prostate Imaging System is a receive-only coil intended for use as a Magnetic Resonance Diagnostic Device (MRDD) for high-resolution magnetic resonance imaging, including spectroscopy, of the human prostate gland and surrounding pelvic tissue. The 3.0T Prostate Imaging System is intended for use with Siemens 3.0T Trio scanner platforms only. Only trained healthcare professionals are intended to operate this device.

DEVICE DESCRIPTION AND COMPARISON TO UNMODIFIED PREDICATE:

The MEDRAD 3.0T Prostate Imaging System maintains a similar intended use, similar operational parameters, similar labeling and is used in a manner similar to the predicate devices.

The following comparison tables identify the similarities and differences between the new device and the predicate devices.

Comparison of Features and Principles of Operation in MEDRAD 1.5T Endorectal Prostate Coil and Flex Interface Device (Predicates) and MEDRAD 3.0T Prostate Imaging System (Proposed)

Feature	(Predicates) MEDRAD 1.5T Endorectal Coil and MEDRAD Flex Interface Device	(Proposed) 3.0T Prostate Imaging System
Coil Type	Receive-only surface coil.	Receive-only surface coil.
Region of Interest	Prostate gland and surrounding tissue.	Prostate gland and surrounding tissue.
System connection	6-pin DIN connector from interface device to scanner.	Circular RF keyed connector from interface device to scanner.
Endorectal Coil Compatibility	1.5T MRI scanner platforms.	3.0T MRI scanner platforms.
Interface Device Compatibility	Siemens Vision 1.5T MRI scanners.	Siemens 3.0T Trio MRI scanners.
Decoupling	Active and passive (interface device).	Passive (endorectal coil); active and passive (interface device).
Tuning	Fixed tuning set in production.	Fixed tuning set in production.
RF Signal Pre-Amplification	Performed by the scanner.	Performed by the interface device.
Endorectal Coil Inner Balloon Inflation Compatibility	Air.	Air or fluid.

Comparison of Patient-Contacting Materials in MEDRAD 1.5T Endorectal Prostate Coil (Predicate) and MEDRAD 3.0T Endorectal Prostate Coil (Proposed)

	(Predicate) MEDRAD 1.5T Endorectal Prostate Coil	(Proposed) MEDRAD 3.0T Endorectal Prostate Coil
Outer balloon	Natural Latex	Natural Latex
Shaft	PVC	PVC
Shrink tubing	Teflon (FEP)	Teflon (FEP)
Migration stop (affixes to shaft)	PVC	PVC



JUN 23 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa A. Ewing
Regulatory Affairs Specialist
MEDRAD, Inc.
One Medrad Drive
INDIANOLA PA 15051

Re: K051349
Trade/Device Name: MEDRAD 3.0T Prostate
Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance
- diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: May 23, 2005
Received: May 24, 2005

Dear Ms. Ewing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other	-	240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K051349

Device Name: MEDRAD 3.0T Prostate Imaging System

Indications for Use:

The 3.0T Prostate Imaging System is a receive-only coil intended for use as a Magnetic Resonance Diagnostic Device (MRDD) for high-resolution magnetic resonance imaging, including spectroscopy, of the human prostate gland and surrounding pelvic tissue. The 3.0T Prostate Imaging System is intended for use with Siemens 3.0T Trio scanner platforms only. Only trained healthcare professionals are intended to operate this device.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K051349

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